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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,818	06/20/2003	John Claude Krusz	JCK-LEV-1	9233

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EXAMINER	
OLSON, ERIC	

ART UNIT	PAPER NUMBER
1623	

DATE MAILED: 03/30/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/600,818	KRUSZ, JOHN CLAUDE	
	Examiner	Art Unit	
	Eric S. Olson	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Action

Application Data

This action claims benefit of provisional application 690/317, filed 6/20/2002. Claims 1-10 are pending in this application and examined on the merits herein.

Information Disclosure Statement

Applicant has not filed an Information Disclosure Statement (form PTO-1449). If the Applicant wishes for references cited in the Specification to be considered in the examination of the claims, a proper Information Disclosure Statement must be filed along with printed copies of each non-patent document the Applicant wishes the Examiner to consider.

Claim Rejections – 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8 are rejected under 35 U.S.C. 102(b) as being anticipated by Lamberty et. al. (WIPO International Patent Application Publication WO 01/39779 A1, published June 7, 2001, more than a year before the effective filing date of the application under consideration, included in PTO-892).

Lamberty et. al. disclose that, "**levetiracetam** possesses therapeutic properties which render it **particularly useful in the treatment and prophylaxis** of bipolar disorders, mania, **migraine**, and chronic or neuropathic pain." (p. 1, lines 25-27) In addition, Claim 1 of Lamberty et. al. teaches, "**Use of levetiracetam** for the manufacture of a medicament for treatment of bipolar disorders, mania, **migraine**, and chronic or neuropathic pain." (p. 40, lines 3-4) According to Lamberty et. al., Claim 2 teaches, "A pharmaceutical composition for the treatment of bipolar disorders, mania, **migraine**, and chronic or neuropathic pain comprising **a therapeutically effective amount of levetiracetam and a pharmaceutically acceptable carrier**." (p. 40, lines 6-8) Lamberty et. al. define "migraine" as referring to, "a disorder characterized by **recurrent attacks of headache** that vary widely in intensity, frequency, and duration." (p. 2, lines 7-8) Regarding method of administration, Lamberty et. al. teaches, "Pharmaceutical compositions comprising levetiracetam can, for example, be administered **orally** or parenterally, e.g. **intravenously**, intramuscularly, or subcutaneously or intrathecally." (p. 10 lines 13-15), as well as, "Pharmaceutical compositions which can be used for **parenteral administration** are in the pharmaceutical forms which can be used for this mode of administration and are in the form of **aqueous or oily solutions or suspensions** generally contained in..." (p. 10, lines 30-33). This reference clearly discloses that levetiracetam is useful for the treatment of migraine headaches, a teaching which clearly anticipates the claimed methods of claims 1, and 4-7 for treating either recurrent or acute headaches with oral or injectable levetiracetam. The language in said reference anticipates any use of

levetiracetam for the treatment of migraine headaches, including both daily oral administration and acute intravenous injection.

Regarding dosage, Lamberty et. al. teaches, "the dosage unit is in the range 50 to 3000 milligrams(mg) and **more preferably in the range 250 to 1500 mg of levetiracetam**." (p. 11, lines 16-18) and, "The primary objective of this therapeutic exploratory study is to evaluate the efficacy and safety of **750 mg b.i.d. levetiracetam** for the prevention of migraine headache," (p. 25, lines 28-30). Thus the reference anticipates the dosages stated in claims 2 and 3.

Claim 2 of Lamberty et. al. also clearly claims the pharmaceutical composition of claim 8 of the instant application, which is accurately described as a "pharmaceutical composition for the treatment of migraine, comprising a therapeutically effective amount of levetiracetam and a **pharmaceutically acceptable carrier**," (p. 40, claim 2, lines 6-8) as sterile water is clearly a pharmaceutically acceptable carrier for any water-soluble pharmaceutical composition.

Lamberty et. al. thus anticipate the claimed inventions of claims 1-8.

Claim 8 is rejected under 35 U.S.C. 102(b) as being anticipated by Hannon et. al., (*Seizure*, 2001, vol. 10 p. 287-293, included in PTO-892).

Hannon et. al. describe, on p. 289, left column, second paragraph, under the heading "Drugs", the preparation of an aqueous injectable solution of levetiracetam in saline, which falls within the claim language of claim 8, "comprising a **sterile aqueous injectable** formulation that contains levetiracetam as an active therapeutic agent."

Therefore the pharmaceutical composition taught by Hannon et. al. falls within the bounds of claim 8.

Hannon et. al. thus anticipate the claimed invention of claim 8.

Claim Rejections – 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WIPO International Patent Application Publication WO 01/39779 A1, published June 7, 2001 as well as Hannon et. al., (*Seizure*, 2001, vol. 10 p. 287-293), in view of the teaching of the pharmacology textbook, Remington: The Science and Practice of Pharmacy, (PTO-892 attached), herein referred to as Remington, and further in view of an FDA memorandum concerning the labeling of analgesic drugs (available at PTO-892 attached, herein referred to as FDA).

As described previously, Lamberty et. al. and Hannon et. al. both teach a sterile aqueous injectable solution of levetiracetam. They do not explicitly teach a sealed vial containing a sterile aqueous injectable solution of levetiracetam packaged with printed

instructions indicating that the enclosed solution is useful for the treatment of headaches.

Remington (Chapter 41, p. 800) teaches a method of packaging pharmaceutical compositions involving a vial sealed with a rubber stopper held in place by an aluminum cap. Such a vial is used to preserve a sterile liquid formulation during storage.

FDA describes the regulations in place in the year 1994 concerning the labeling of over-the-counter analgesic drugs. In particular, the first page of the reference contains a table describing the standard of proof required for the label and packaging of an over-the-counter analgesic medication to be allowed to include headache as a treatable indication. This memorandum attests to the fact that, in the year 1994, before the time of the disclosed invention, analgesic medications capable of relieving headache were packaged with a printed label indicating that they were useful for the treatment of headache.

Therefore, it would have been obvious to one of ordinary skill in the art at the time of the invention to modify the teachings of Lamberty et. al and Hannon et. al. by packaging the sterile aqueous solution of levetiracetam in a sealed vial and including, either printed on the vial or on instructions packaged with the vial, that the enclosed medication is useful for the treatment of recurrent acute headaches. One would have been motivated to modify the original invention in this manner in order to preserve the sterility of the drug during storage, and to inform physicians and patients using the drug that it is useful for the treatment of recurring acute headaches.

Further, a pharmaceutical composition packaged with directions for administering the composition is deemed obvious since it is within the knowledge and conventional skills of a pharmacologist to conveniently assist the user and prescriber for easy dispensary of the medication. Moreover, the inclusion of package inserts including "indication and use" of the pharmaceutical composition in a pharmaceutical kit is mandated by 21 CFR 201.57 according to *Remington: The Science and Practice of Pharmacy*. Furthermore, with respect to the instructions or directions that direct one on how to use in a kit, the U.S. Court of Appeals for the Federal Circuit, *In re Ngai* 03-1524, recently rules that a kit of the prior art with a set of instructions is unpatentable (see the precedential opinion issued May 13, 2004).

Therefore the inventions of claims 9 and 10 taken as a whole are *prima facie* obvious.

Conclusion

No claims are allowed in this application.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric S. Olson whose telephone number is 571-272-9051. The examiner can normally be reached on Monday through Friday from 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on Monday through Friday from 8:30-

5:00. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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3/24/06

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